

REMARKS

Claims 1-5, 26, 28, 30, and 37-42, as amended, appear in this application for the Examiner's review and consideration. Claims 6, 7, 27, 29, and 31-36, and 43-48 have been canceled without prejudice. Applicants fully reserve their rights to prosecute the subject matter of any cancelled claim in one or more continuation, continuation-in-part, or divisional applications. Claims 1 and 37 have been amended to more particularly point out the claimed subject matter and to correct inadvertent minor spelling and editorial errors, but no new matter has been added. Claims 1 and 37 have been amended to recite a composition having a conductive impedance value between 600 ohm to 22500 ohm measured at 100 Hz to 100 kHz. The amendment to claims 1 and 37 is supported in the specification at Table 1 and p. 21, ll. 21-29. The amendment to claim 3 is supported in the specification at p. 9, ll. 23-24.

Objections to the Claims

In the Office Action, claims 2 and 29 were objected to due to the informality set forth on page 3 of the Office Action. Applicants have cancelled claim 29, thereby making the objection moot.

Rejection of the Claims under 35 U.S.C. § 112, second paragraph

Claims 30, 35, 41 and 46 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the reasons set forth on page 3 of the Office Action. Applicants respectfully traverse. Claims 30 and 41 have been amended, while claims 35 and 46 have been cancelled, rendering this rejection moot. Thus, the rejection of claims 30 and 41 under 35 U.S.C. § 112, second paragraph, cannot stand and should be withdrawn.

Rejection of the Claims under 35 U.S.C. § 102/103

Claims 1-7 and 26-48 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated or in the alternative under 35 U.S.C. § 103(a) as allegedly being rendered obvious by U.S. patent No. 5,354,790 to Keusch *et al.* ("the '790 patent") for the reasons set forth at pages 4-6 of the Office Action. Applicants respectfully traverse.

It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231

U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987). Although the use of additional references to confirm the contents of an allegedly anticipating reference is permitted, anticipation does not permit an additional reference to supply a missing claim limitation.

Teleflex, Inc. v. Ficosa North American Corp., 299 F.3d 1313 (Fed. Cir. 2002).

The consistent criterion for determination of obviousness is whether the prior art would have suggest to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). As the Examiner is well aware, in order to form a proper basis for a rejection under 35 U.S.C. § 103, the prior art must provide some suggestion, either explicit or implicit, of the combination that allegedly renders a claimed invention obvious. *M.P.E.P.*, § 2142 (June 1998), *see also*, *Panduit Corp. v. Denisson Manufacturing Co.*, 1 U.S.P.Q.2d 1593, 1597 (Fed. Cir. 1987). The Examiner can satisfy the burden of showing obviousness of the combination only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Sang Su Lee*, 277 F.3d 1338, 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002); citing *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The need for specificity is paramount, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected the components for combination in the manner claimed. *Id.* The Examiner's conclusory statements do not adequately address the issue of motivation to combine; the factual question of motivation is material to patentability, and can not be resolved on subjective belief and unknown authority. *Id.*

The '790 patent discloses a non-stringy adhesive hydrogel which is more cohesive than it is adhesive to human skin comprised of a cohesive homogeneous mixture of water and at least one polymer which polymer is present in a concentration of at least about 7% by weight to less than about 35 weight percent of the mixture and which aqueous mixture had been exposed to a dose of radiant energy effective to provide substantially featureless force-displacement (AED) value of at least about 5 to less than about 50g/cm. *See*, the '790 patent col. 6, l. 65 to col. 7, l. 15. The highly conductive non-stringy adhesive hydrophilic gel has an amount of a water-soluble electrolyte effective to reduce the transverse electrical resistance of the aqueous mixture

to an impedance at 10-60 Hz of less than about 1,000 ohms, preferably less than about 100 ohms. *Id.* at col. 8, ll. 11-21.

The '790 patent fails to anticipate the present claims because each element is not described in the reference. Particularly, the '790 patent fails to recite a composition having a conductive impedance value between 600 ohm to 22500 ohm measured at 100 Hz to 100 kHz when used as a coating on an implantable cardiac stimulus electrode.

Alternatively, the '790 patent fails to render obvious the present claims because it teaches away from the recited claims. The '790 patent teaches a non-stringy adhesive hydrogel having an amount of a water-soluble electrolyte effective to reduce the transverse electrical resistance of the aqueous mixture to an impedance at 10-60 Hz of less than about 1,000 ohms. The preferred resistance is less than 1,000 ohms, it is explicitly recited to be less than about 100 ohms. The present claims, however, disclose a composition having an impedance of 600 ohm to 22500 ohm as measured at 100 Hz to 100 kHz. The '790 patent explicitly teaches to reduce the amount of resistance, to amounts well below the maximum range of the present claims. In fact, the preferred 100 ohm range is outside the recited range of the present claims. Accordingly, a skilled artisan would have no motivation to increase the resistance of the '790 patent composition, as it is taught not to do so. Moreover, the skilled artisan would have no reasonable expectation of success to increase the composition resistance as this would deviate from the explicit teachings of the '790 patent.

Consequently, the '790 patent does not anticipate or, in the alternative, render obvious the present claims. Accordingly, the rejection of claims 1-7 and 26-48 under 35 U.S.C. § 102(b) as anticipated or § 103(a) as being rendered obvious by the '790 patent cannot stand and should be withdrawn.

Claims 1-4, 26, 29, 31-33, 37, 39, 43, and 47 stand rejected under 35 U.S.C. § 102(e/a) as allegedly being anticipated by Russian patent No. 2,086,217 to Dolzhikov *et al.* ("the '217 patent"), as described in the abstract, for the reasons set forth on pages 6 and 7 of the Office Action. Applicants respectfully traverse.

The '217 patent discloses a composition for protecting corneal epithelium during the emergency eye surgery consisting of a 0.5-10 weight % solution of polyethylene oxide, in a balanced acetate-nitrate or phosphate buffer of pH of 6.8-7.8. *See*, abstract.

The '217 patent fails to anticipate the present claims because each and every element of the claims is not present in the reference. Particularly, the '217 patent fails to recite a polymer having a molecular weight from about 100,000 to about 10,000,000 daltons and which is not adhesive. Furthermore, the '217 patent does not recite a composition which has a conductive impedance value between 600 ohm to 22500 ohm measured at 100 Hz to 100 kHz when used as a coating on an implantable cardiac stimulus electrode.

Accordingly, the rejection of claims 1-4, 26, 29, 31-33, 37, 39, 43, and 47 under 35 U.S.C. § 102(e/a) as anticipated by the '217 patent cannot stand and should be withdrawn.

Claims 1-7 and 26-48 stand rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious over the '217 patent and further in view of U.S. patent No. 4,515,162 ("the '162 patent") to Yamamoto *et al.* or No. 5,576,072 to Hostettler *et al.* ("the '072 patent") for the reasons set forth on pages 7 and 8 of the Office Action. Applicants respectfully traverse.

The '217 patent fails to render the present claims obvious, because, as discussed above, elements of the recited claims are absent from the reference and there is no suggestion to modify the teachings of the reference to obtain the present claims. The '217 patent does not disclose or suggest a polymer having any particular molecular weight, much less a molecular weight of 100,000 to about 10,000,000 daltons as recited in the present claims. The abstract alone provides no guidance as to the polymer molecular weight, in fact, the '217 patent fails to disclose this property as being of any importance. Consequently, the skilled artisan has no motivation to determine the molecular weight of the present claims. Additionally, the '217 does not disclose or suggest either explicitly or implicitly a composition that has a conductive impedance value between 600 ohm to 22500 ohm measured at 100 Hz to 100 kHz. In fact, the '217 patent is silent as to this property and accordingly cannot teach that which it does not know. Therefore, the skilled artisan, once again, has no motivation to alter the properties of the composition to obtain the composition of the recited claims.

To remedy the deficiencies of the '217 patent, the Office Action cites the '162 patent. The '162 patent discloses a hydrogel prepared from a hydrophilic polymer, water, and a cross-linking component, wherein the polymer is at least one of polyacrylic acid and a polyacrylic acid salt, and the cross-linking component is a compound containing at least 2 epoxy groups in the molecule. *See*, the '162 patent col. 2, ll. 8-15. When used as an electrode pad, to

improve the peelability of the hydrogel from the body after use, at least one layer composed of woven fabric or net-like nonwoven fabric is placed in the hydrogel pad. *Id.* at col. 3, ll. 23-34.

The '162 patent fails to remedy the deficiencies of the '217 patent for several reasons. The '162 patent fails to disclose or suggest either implicitly or explicitly a composition that has a conductive impedance value between 600 ohm to 22500 ohm measured at 100 Hz to 100 kHz. In fact, the '162 patent is silent about any electrical conductivity, resistance, or impedance of the disclosed hydrogel. Additionally, the combination of the two references requires the skilled artisan to selectively pick and choose without any motivation from various components to obtain the present invention. As discussed above, the '162 patent teaches using a net-like non-woven fabric. The '217 patent makes no mention of such a fabric. Therefore, when the references are combined, the skilled artisan must pick without any motivation other than the present claims either to include the non-woven fabric or not to include the fabric. The skilled artisan has neither guidance nor any reasonable expectation of success that the random ad hoc selection of components would result in any invention. The only motivation for the combination are the present claims, which are unavailable to the skilled artisan when making the choice.

Alternatively, the Office Action cites the '072 patent to remedy the deficiencies of the '162 patent, however, this is unavailing. The '072 patent discloses coatings that include hydrophilic polyurethane/polyurea prepolymer intermediates which are cohesively attached to an organic plastic or rubber polymer substrates or metal substrates which when exposed to an aqueous solution of one or more dissimilar hydrogel polymers which are water-soluble polysaccharides, water-soluble salts thereof, or water soluble polyoxyethylenes, cause the resulting commingled hydrogel coatings to form lubricating films on an apparatus. *See*, the '072 patent col. 10, ll. 10-25. Useful starting prepolymer intermediates include hydrophilic polyurethane prepolymer intermediates derived from water-soluble polyether polyols and organic polyisocyanates. *Id.* at ll. 41-46.

Like the '162 patent and the '217 patent, the '072 patent fails to render the present claims obvious as it does not disclose or suggest a composition having a composition that has a conductive impedance value between 600 ohm to 22500 ohm measured at 100 Hz to 100 kHz. In fact, the '072 patent emphasis the importance of plasma treatment of the materials, but never discloses or suggests electrical conductivity as a desirable property of the polymer. Furthermore,

the skilled artisan in view of the combination of the '162 patent and the '072 patent, cannot determine with any reasonable expectation of success the appropriate combination of variables to obtain the present claims. As the '072 patent is silent as to polymeric electrical conductivity, resistance, or impedance, the skilled artisan must wonder whether the variable is desirable in the combination of references.

Accordingly, the rejection of claims 1-7 and 26-48 under 35 U.S.C. § 103(a) as rendered obvious by the '217 patent in view of the '162 patent or the '072 patent cannot stand and should be withdrawn.

Conclusion

Accordingly, it is believed that claims 1-7 and 26-48 are now in condition for allowance, early notice of which would be appreciated. If any outstanding issues remain, the examiner is invited to telephone the undersigned at (612-371-2160) to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required or credit overpayments due, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5 day of May, 2003.

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